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FEDERAL SECURITY AGENCY

✓ FOOD AND DRUG ADMINISTRATION

✓ SERVICE AND REGULATORY ANNOUNCEMENTS

✓ IMPORT MILK, No. 1, Rev. 1

✓ REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL IMPORT MILK ACT

INTRODUCTION

This informal print of the regulations promulgated in 1927 to carry out the purposes of the Federal Import Milk Act differs from the 1927 print only in the changes in terms resulting from Reorganization Plan No. IV, under which the Food and Drug Administration and its functions were transferred to the Federal Security Agency and the functions of the Secretary of Agriculture relating to the administration of five acts, including the Federal Import Milk Act, were transferred so as to be exercised by the Federal Security Administrator. The Plan also changed the name of the Chief of the Food and Drug Administration to Commissioner of Food and Drugs.

OSCAR R. EWING,
Federal Security Administrator.

Washington, D. C., February 27, 1948.

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REGULATIONS

Regulation 1.—SHORT TITLE OF THE ACT

For the purposes of these regulations the act "To regulate the importation of milk and cream into the United States for the purpose of promoting the dairy industry of the United States and protecting the public health" shall be known and referred to as "the Federal Import Milk Act."

Regulation 2.—SCOPE OF THE ACT

The provisions of the act apply to all milk and cream offered for import into the continental United States.

Regulation 3.—DEFINITIONS

For the purposes of this act and of these regulations:

(a) Milk is the whole, fresh, clean, lacteal secretion obtained by the complete milking of one or more healthy cows, properly fed and kept, excluding that obtained within 15 days before and 5 days after calving, or such longer period as may be necessary to render the milk practically colostrum free.

(b) Cream is that portion of milk, rich in milk fat, which rises to the surface of milk on standing or is separated from it by centrifugal force.¹

(c) Condensed milk, as the term is used in section 3, paragraph 2, includes evaporated milk in the manufacture of which sterilization of the milk and cream is a necessary and usual process; it includes sweetened condensed milk only if it is prepared by a process which insures sterilization of the milk and cream. Condensed milk, as the term is used in section 3, paragraph 3, means sweetened condensed milk.

(d) Evaporated milk is the product resulting from the evaporation of a considerable portion of the water from milk, or from milk with adjustment, if necessary, of the ratio of fat to nonfat solids by the addition or by the abstraction of cream. It contains not less than seven and eight-tenths percent (7.8%) of milk fat nor less than twenty-five and five-tenths percent (25.5%) of total milk solids; *Provided, however,* That the sum of the percentages of milk fat and total milk solids be not less than thirty-three and seven-tenths (33.7).²

(e) Sweetened condensed milk is the product resulting from the evaporation of a considerable portion of the water from milk to which sugar (sucrose) has been added. It contains not less than twenty-eight percent (28%) of total milk solids and not less than eight percent (8%) of milk fat.³

(f) Pasteurization is the process whereby every particle of milk or cream is subjected to a temperature not lower than 142° F. for not less than 30 minutes, after which the product is promptly cooled to 50° F. or lower.

(g) A shipper is anyone, other than a common carrier, who ships, transports, or causes to be shipped or transported into the United States milk or cream owned by him.

(h) Administrator means the Federal Security Administrator.

(i) Commissioner means the Commissioner of Food and Drugs.

¹ But see 21 CFR Cum. Supp. 18.500 to 18.515, incl. (reprinted in S. R. A., F. D. C. 2 "Definitions and Standards for Food").

² But see 21 CFR Cum. Supp. 18.520 (reprinted in S. R. A., F. D. C. 2 "Definitions and Standards for Foods").

³ But see 21 CFR Cum. Supp. 18.530 (reprinted in S. R. A., F. D. C. 2 "Definitions and Standards for Foods").

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Regulation 4.—PHYSICAL EXAMINATION OF COWS

Physical examination of any and all cows in herds producing milk or cream which is to be shipped or transported into the United States shall be made by an authorized veterinarian of the United States or of any State or municipality thereof or of the country in which such milk or cream is produced to determine whether such cow or cows are in a healthy condition. Such examination shall be made as often as the Administrator may deem necessary and, in any event, shall have been made within one year previous to the time of the importation.

The result of the physical examination shall be set forth in the form prescribed by the Administrator.

Regulation 5.—TUBERCULIN TEST

Except as provided in regulation 16, any and all animals in herds producing milk or cream which is to be shipped or transported raw into the United States shall be free from tuberculosis, as determined by a tuberculin test applied by an official veterinarian of the United States or of any State or municipality thereof or of the country in which such milk or cream is produced. Such test shall be made as often as the Administrator may deem necessary and, in any event, shall have been made within one year previous to the time of the importation. All animals showing positive or suspicious reactions to the tuberculin test must be permanently removed from the herd.

The results of the tuberculin test and all facts concerning the disposal of reacting or suspected animals shall be set forth in the form prescribed by the Administrator.

Regulation 6.—SANITARY INSPECTION OF DAIRY FARMS

The sanitary conditions of any dairy farm producing milk or cream to be shipped or transported into the United States or to a plant from which milk or cream is to be shipped or transported into the United States must score at least 50 points out of 100 points, according to the methods for scoring as provided by the score card for sanitary inspection of dairy farms used by the Bureau of Dairy Industry of the United States Department of Agriculture at the time of scoring.

Regulation 7.—SANITARY INSPECTION OF PLANTS

The sanitary conditions of any plant handling milk or cream any part of which is to be shipped or transported into the United States shall score at least 50 points out of 100 points according to the methods for scoring as provided by the score card for sanitary inspection of such plants used by the Bureau of Dairy Industry of the United States Department of Agriculture at the time of scoring.

Regulation 8.—SCORING

Scoring of sanitary conditions required by regulations 6 and 7 shall be done by an official inspector of the United States or of any State or municipality thereof or of the country in which the dairy farm or plant is located.

Regulation 9.—PASTEURIZATION—EQUIPMENT AND METHODS

All dairy farms and plants at which any milk or cream is pasteurized for shipment or transportation into the United States shall employ adequate pasteurizing machinery of a type easily cleaned and of sanitary construction capable

of holding every portion of the milk or cream at the required temperature for the required time. Such pasteurizing machinery shall be properly equipped with accurate time and temperature recording devices, which shall be kept at all times in good working order. The temperature at the time of heating and holding must invariably be recorded on thermograph charts, initialed, numbered, and dated by the official having jurisdiction over such farms and plants. All thermograph charts shall be held for a period of one year unless within that period they have been examined and released by such authorized agents as are designated by the Administrator.

Regulation 10.—METHOD OF BACTERIAL COUNT

The bacterial count of milk and cream refers to the number of viable bacteria as determined by the standard plate method of the American Public Health Association in use at the time of the examination.

Regulation 11.—AUTHORITY TO SAMPLE AND INSPECT

Inspectors engaged in the enforcement of the act are empowered to test for temperature, to take samples of milk or cream, and to use such means as may be necessary for these purposes.

Regulation 12.—PERMITS FOR PASTEURIZED MILK OR CREAM

Permits to ship or transport pasteurized milk or cream into the United States will be granted only upon compliance with the requirements of clauses 1 and 3 of section 2 of the act, regulation 4 and regulations 6 and 7, as applicable.

Regulation 13.—PERMITS FOR RAW MILK OR CREAM

Except as provided in regulation 16, permits to ship or transport raw milk or cream into the United States will be granted only when the milk or cream comes from dairy farms or plants where pasteurization is not carried on and then only upon compliance with the requirements of clauses 1, 2, and 3 of section 2 of the act, regulations 4 and 5 and regulations 6 and 7, as applicable.

Regulation 14.—PERMITS GRANTED ON CERTIFICATES

In the discretion of the Administrator, a permit may be granted on a duly certified statement signed by a duly accredited official of an authorized department of any foreign government or of any State of the United States or any municipality thereof. Such statement shall be in the form of a certificate prescribed by the Administrator and shall have attached thereto, as a part thereof, signed copies of reports prescribed by regulations 4, 5, and also by regulations 6 and 7, as applicable. The necessary inspections and examinations upon which the reports are based shall be made by persons who are acting under the direct supervision of the certifying official.

Regulation 15.—PERMITS WAIVING CLAUSE 4, SECTION 2

The Administrator, in his discretion, will issue to a shipper who is an operator of a condensery a permit waiving the requirements of clause 4 of section 2 of the act and allowing milk and cream containing not to exceed 1,200,000 bacteria per cubic centimeter to be shipped or transported into the United States if the condensery is located within a radius of 15 miles of the point of production of the milk and cream and such milk and cream are to be sterilized in the manufacture of condensed milk.

Regulation 16.—PERMITS WAIVING CLAUSES 2 AND 5, SECTION 2

A permit to ship or transport raw milk into the United States will contain a waiver of clauses 2 and 5 of section 2 of the act when the shipper is an operator of a creamery or condensery, or is a producer shipping or transporting to a creamery or condensery, and the creamery or condensery is located in the United States within a radius of 20 miles of the point of production of such milk, and the milk, prior to its sale, use, or disposal, is pasteurized, condensed, or evaporated.

Regulation 17.—TEMPORARY PERMITS

A temporary permit will be granted only upon a satisfactory showing that the applicant therefor has been unable to obtain the necessary inspections required by the applicable provisions of section 2 of the act. Temporary permits shall be valid until the Administrator shall provide for inspection to ascertain that clauses 1, 2, and 3 of section 2 of the act have been complied with.

Regulation 18.—EXAMINATIONS AND INSPECTIONS MUST BE ALLOWED

Dairy farms and plants from which milk or cream is shipped or transported into the United States shall be open at all reasonable times to authorized agents for necessary examinations and inspections. Failure to permit such examinations and inspections may be considered cause for the suspension or revocation of the permit.

Regulation 19.—APPLICATION FOR PERMIT

Application for a permit to ship or transport milk or cream into the United States shall be made by the actual shipper upon forms prescribed by the Administrator. The request for forms of applications for permits should be addressed to Commissioner of Food and Drugs, Food and Drug Administration, Federal Security Agency, Washington 25, D. C.

Regulation 20.—PERMIT NUMBER

Each permit issued under this act, including each temporary permit, shall bear an individual number. The right to the use of such number is restricted solely to the permittee.

Each container of milk or cream shipped or transported into the United States by such permittee shall have firmly attached thereto a tag in the following form, bearing the required information in clear and legible type:

Product _____
 (State whether raw milk, pasteurized milk, raw cream, or pasteurized cream.)

Permit number _____
 Federal Import Milk Act.
 Federal Security Agency.

Shipper _____
 Address of shipper _____

Provided, That in case of unit shipments consisting of milk only or cream only under one permit number, in lieu of each container being so marked, the vehicle of transportation, if sealed, may be tagged with the above tag, which should in addition show the number of containers and the quantity of contents of each.

Regulation 21.—SUSPENSION AND REVOCATION OF PERMIT

A permit to ship or transport milk or cream into the United States may be suspended for cause at any time. A permit may be revoked for cause after opportunity to be heard has been accorded the permittee, who may appear in person, by attorney, or by letter and show cause why the permit should not be revoked.

Regulation 22.—HEARING BEFORE PROSECUTION

Before the violation of the act is referred to the Department of Justice for prosecution under section 5, an opportunity to be heard will be given to the party against whom prosecution is under consideration. The hearing will be private and confined to questions of fact. The party notified may present evidence, either oral or written, in person or by attorney, to show cause why he should not be prosecuted. After a hearing is held, if it appears that the law has been violated, the facts will be reported to the Department of Justice.

FEDERAL IMPORT MILK ACT

[PUBLIC—No. 625—69TH CONGRESS]

[H. R. 11768]

An Act To regulate the importation of milk and cream into the United States for the purpose of promoting the dairy industry of the United States and protecting the public health.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That on and after the date on which this Act takes effect the importation into the United States of milk and cream is prohibited unless the person by whom such milk or cream is shipped or transported into the United States holds a valid permit from the Federal Security Administrator.

SEC. 2. Milk or cream shall be considered unfit for importation (1) when all cows producing such milk or cream are not healthy and a physical examination of all such cows has not been made within one year previous to such milk being offered for importation; (2) when such milk or cream, if raw, is not produced from cows which have passed a tuberculin test applied by a duly authorized official veterinarian of the United States, or of the country in which such milk or cream is produced, within one year previous to the time of the importation, showing that such cows are free from tuberculosis; (3) when the sanitary conditions of the dairy farm or plant in which such milk or cream is produced or handled do not score at least fifty points out of one hundred points according to the methods for scoring as provided by the score cards used by the Bureau of Dairy Industry of the United States Department of Agriculture at the time such dairy farms or plants are scored; (4) in the case of raw milk if the number of bacteria per cubic centimeter exceeds three hundred thousand and in the case of raw cream seven hundred and fifty thousand, in the case of pasteurized milk if the number of bacteria per cubic centimeter exceeds one hundred thousand, and in the case of pasteurized cream five hundred thousand; (5) when the temperature of milk or cream at the time of importation exceeds fifty degrees Fahrenheit.

SEC. 3. The Federal Security Administrator shall cause such inspections to be made as are necessary to insure that milk and cream are so produced and handled as to comply with the provisions of section 2 of this Act, and in all cases when he finds that such milk and/or cream is produced and handled so as not to be unfit for importation under clauses 1, 2, and 3 of section 2 of this Act, he shall issue to persons making application therefor permits to ship milk and/or cream into the United States: *Provided*, That in lieu of the inspections to be made by or under the direction of the Federal Security Administrator he may, in his discretion, accept a duly certified statement signed by a duly accredited official of an authorized department of any foreign government and/or of any State of the United States or any municipality thereof that the provisions in clauses 1, 2, and 3 of section 2 of this Act have been complied with. Such certificate of the accredited official of an authorized department of any foreign government shall be in the form prescribed by the Federal Security Administrator, who is hereby authorized and directed to prescribe such form, as well as rules and regulations regulating the issuance of permits to import milk or cream into the United States.

The Federal Security Administrator is hereby authorized, in his discretion, to waive the requirement of section 2, paragraph 4, of this Act when issuing permits to operators of condenseries in which milk and/or cream is used when sterilization of the milk and/or cream is a necessary process: *Provided, however*, That no milk and/or cream shall be imported whose bacterial count per cubic centimeter in any event exceeds one million two hundred thousand: *Provided further*, That such requirements shall not be waived unless the farm producing such milk to be imported is within a radius of fifteen miles of the condensery in which it is to be processed: *Provided further*, That if milk and/or cream imported when

the requirements of section 2, paragraph 4, have been so waived, is sold, used, or disposed of in its raw state or otherwise than as condensed milk by any person, the permit shall be revoked and the importer shall be subject to fine, imprisonment, or other penalty prescribed by this Act.

The Federal Security Administrator is directed to waive the requirements of paragraphs 2 and 5 of section 2 of this Act in so far as the same relate to milk when issuing permits to operators of, or to producers for delivery to, creameries and condensing plants in the United States within twenty miles of the point of production of the milk, and who import no raw milk except for pasteurization or condensing: *Provided*, That if milk imported when the requirements of paragraphs 2 and 5 of section 2 have been so waived is sold, used, or disposed of in its raw state, or otherwise than as pasteurized, condensed, or evaporated milk by any person, the permit shall be revoked and the importer shall be subjected to fine, imprisonment, or other penalty prescribed by this Act.

The Federal Security Administrator is hereby authorized and directed to make and enforce such regulations as may in his judgment be necessary to carry out the purpose of this Act for the handling of milk and cream, for the inspection of milk, cream, cows, barns, and other facilities used in the production and handling of milk and/or cream and the handling, keeping, transporting, and importing of milk and/or cream: *Provided, however*, That unless and until the Federal Security Administrator shall provide for inspections to ascertain that paragraphs 1, 2, and 3 of section 2 have been complied with, the Federal Security Administrator shall issue temporary permits to any applicants therefor to ship or transport milk and/or cream into the United States.

The Federal Security Administrator is authorized to suspend or revoke any permit for the shipment of milk or cream into the United States when he shall find that the holder thereof has failed to comply with the provisions of or has violated this Act or any of the regulations made hereunder, or that the milk and/or cream brought or shipped by the holder of such permit into the United States is not produced and handled in conformity with, or that the quality thereof does not conform to, all of the provisions of section 2 of this Act.

SEC. 4. It shall be unlawful for any person in the United States to receive milk or cream imported into the United States unless the importation is in accordance with the provisions of this Act.

SEC. 5. Any person who knowingly violates any provision of this Act shall, in addition to all other penalties prescribed by law, be punished by a fine of not less than \$50 nor more than \$2,000, or by imprisonment for not more than one year, or by both such fine and imprisonment.

SEC. 6. There is hereby authorized to be appropriated, out of any moneys in the Treasury not otherwise appropriated, the sum of \$50,000 per annum, to enable the Federal Security Administrator to carry out the provisions of this Act.

SEC. 7. Any laws or parts of laws inconsistent herewith are hereby repealed.

SEC. 8. Nothing in this Act is intended nor shall be construed to affect the powers of any State, or any political subdivision thereof, to regulate the shipment of milk or cream into, or the handling, sale, or other disposition of milk or cream in, such State or political subdivision after the milk and/or cream shall have been lawfully imported under the provisions of this Act.

SEC. 9. When used in this Act—

(a) The term "person" means an individual, partnership, association, or corporation.

(b) The term "United States" means continental United States.

SEC. 10. This Act shall take effect upon the expiration of ninety days from the date of its enactment.

Approved, February 15, 1927,